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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0014; FRL-9903-88]

Indaziflam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indaziflam in or on coffee, banana, and palm oil. Bayer Crop Science requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0014, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0014 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0014, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 15, 2013 (78 FR 32) (FRL-9378-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8125) by Bayer Crop Science, 2 T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.653 be amended by establishing tolerances for residues of the herbicide indaziflam, N-[(1R, 2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl-1,3,5-triazine-2,4-diamine]-6-(1-fluoroethyl) and its fluoroethyl-indaziflam metabolite, each expressed as the parent compound, in or on coffee at 0.01 part per million (ppm), banana at 0.01 ppm, and palm oil at 0.03 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indaziflam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indaziflam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The nervous system is the major target for indaziflam toxicity in rats and dogs, with the dog being the more sensitive species based on neuropathology (degenerative nerve fibers in the brain, spinal cord and sciatic nerve). Clinical signs of neurotoxicity were observed in the acute, subchronic, and developmental neurotoxicity studies and

consisted primarily of tremors, changes in activity and reactivity, repetitive chewing, dilated pupils, and oral, perianal, and nasal staining. Similar clinical signs of neurotoxicity were observed in the 2-generation reproduction study, the rat chronic toxicity study, and the combined rat carcinogenicity/chronic toxicity study. Neuropathology findings were also observed in the rat manifested as focal/multifocal vacuolation of the median eminence of the brain and the pituitary *pars nervosa* and degenerative nerve fibers in the gasserian ganglion, sciatic nerve, and tibial nerve. Evidence of neurotoxicity was not seen in the mouse.

Other organs affected by indaziflam in mice and rats include the kidney, liver, thyroid, stomach, seminal vesicles, and ovaries. Effects on the kidney were observed following chronic exposure in rats and mice while effects on the liver were observed following chronic exposure in the rat. Effects on the thyroid were only observed in multiple dose rat studies. Chronic exposures also lead to atrophied or small seminal vesicles in male and female mice. However, these effects occurred at higher doses than those at which neurotoxicity was observed in the dog.

Decreased body weight gain was observed in most studies following exposure to indaziflam. There was no evidence of immunotoxicity in the available studies, which included a guideline immunotoxocity study in the rat. No systemic effects were observed in the rat following a 28-day dermal exposure period.

No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits or in a reproduction study in rats. In the rat developmental toxicity study, decreased fetal weight was observed in the presence of maternal effects that included decreased body weight gain and food consumption. No

developmental effects were observed in rabbits up to maternally toxic dose levels. Decreased pup weight and delays in sexual maturation (preputial separation in males and vaginal patency in females) were observed in the rat 2-generation reproductive toxicity study, along with clinical signs of toxicity, at a dose causing parental toxicity that included coarse tremors, renal toxicity and decreased weight gain. In the developmental neurotoxicity study, transiently decreased motor activity (PND 21 only) in male offspring was observed and was considered a potential neurotoxic effect. It was observed at a dose that also caused clinical signs of neurotoxicity along with decreased body weight in maternal animals.

Indaziflam showed no evidence of carcinogenicity in the 2-year dietary rat and mouse bioassays. All genotoxicity studies that were conducted on indaziflam were negative.

Testing in acute lethality studies with indaziflam resulted in low toxicity via the oral, dermal, and inhalation routes of exposure. Indaziflam was not an irritant to eyes Category IV) or skin and was not a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by indaziflam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document *Indaziflam. Human Health Risk Assessment to Support Proposed New Import Tolerances (Without a U.S. Registration) on Banana, Coffee, and Palm Oil* at page 33 in docket ID number EPA-HQ-OPP-2013-0014.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for indaziflam used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Indaziflam for Use in Human Health Risk Assessment.

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

Acute dietary (General population including infants and children)	NOAEL = 7.5 mg/kg/day UF_A = 10x UF_H =10x FQPA SF = 1x	Acute RfD = 0.075 mg/kg/day aPAD = 0.075 mg/kg/day	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Chronic dietary (All populations)	NOAEL= 2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day cPAD = 0.02 mg/kg/day	Chronic Dietary Toxicity Study in Dogs LOAEL = 6/7 mg/kg/day M/F based on nerve fiber degenerative lesions in the brain, spinal cord and sciatic nerve
Incidental oral short-term (1 to 30 days)	NOAEL= 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Incidental oral intermediate-term (1 to 6 months)	NOAEL= 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 7.5 mg/kg/day (dermal absorption factor) = 7.3% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Dermal intermediate-term (1 to 6 months)	Dermal (or oral) study NOAEL = 7.5 mg/kg/day (dermal absorption factor) = 7.3% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 7.5 mg/kg/day	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs

	(Inhalation toxicity considered equivalent to oral toxicity.)UF_A = 10x UF_H = 10x FQPA SF = 1x		LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL= 7.5 mg/kg/day (Inhalation toxicity considered equivalent to oral toxicity.) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve
Cancer (Oral, dermal, inhalation)	No evidence of carcinogenicity. Classified as "Not Likely to be Carcinogenic to Humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligrams/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to indaziflam, EPA considered exposure under the petitioned-for tolerances as well as all existing indaziflam tolerances in 40 CFR 180.653. EPA assessed dietary exposures from indaziflam in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for indaziflam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA)'s 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, the acute dietary assessment assumes 100% crop treated (PCT) along with tolerance or maximum residue level estimates for

indaziflam. It used DEEM-WWEIA analyses to estimate the dietary exposure of the U.S. population and various population subgroups.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, the chronic dietary assessment used the same residue levels, analysis and PCT assumptions used in the acute dietary assessment

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that indaziflam does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for indaziflam. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for indaziflam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of indaziflam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of indaziflam equivalents for acute exposures are estimated to be 84 parts per billion (ppb) for surface water and 3.7 ppb for

ground water. For chronic exposures for non-cancer assessments the estimates are 26 ppb for surface water and 3.7 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 84 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Indaziflam is currently registered for the following uses that could result in residential exposures: Home lawn/turf and gardens/tree uses. There are no new indaziflam residential uses associated with this regulatory action. A re-evaluation of existing indaziflam residential uses was conducted to incorporate updated policies and guidance in place since previous risk assessments. Short-term dermal and inhalation handler exposures for residential are expected for those making applications at their homes and short-term dermal and incidental oral exposures are expected via contact with residues following applications in outdoor home environments. For adults, the highest exposure was from dermal post-application high-contact (playing) activities on treated turf during spray applications. The highest exposure scenarios for children 1<2 years old were from dermal post-application high-contact (playing) and incidental oral exposure from treated turf. These exposure scenarios were then combined to determine a total residential exposure and risk estimate for children to be used for the aggregate assessment. Further

information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found indaziflam to share a common mechanism of toxicity with any other substances, and indaziflam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that indaziflam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicology database for indaziflam consists of developmental toxicity studies in rats and rabbits and a reproduction study in rats. No developmental effects were observed in rabbits up to maternally toxic dose levels. Offspring effects in the developmental toxicity study in rats, developmental neurotoxicity study in rats, and the multigeneration toxicity study in rats only occurred in the presence of maternal toxicity and were not considered more severe than the parental effects. EPA concluded that there is no evidence of increased quantitative or qualitative susceptibility to rat or rabbit fetuses exposed *in utero* and/or post-natally to indaziflam.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for indaziflam is complete.

ii. The endpoints selected for risk assessment are based on and are protective of the neurotoxic effects seen in the guideline studies.

iii. There is no evidence that indaziflam results in increased susceptibility *in utero* in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance or maximum residue levels for residues of concern and assumed 100 PCT. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to indaziflam in drinking water. EPA used similarly conservative assumptions

to assess dermal post-application exposure as well as incidental oral exposure of children. These assessments will not underestimate the exposure and risks posed by indaziflam.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indaziflam will occupy 19% of the aPAD for infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to indaziflam from food and water will utilize 8% of the cPAD for infants <1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of indaziflam is not expected.

3. *Short-and intermediate-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Indaziflam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate

chronic exposure through food and water with short-term residential exposures to indaziflam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,400 for adults (post-application) and 560 for children (post-application). Because EPA's level of concern for indaziflam is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, indaziflam is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to indaziflam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry detection [LC/MS/MS] method (DH-003-P07-02) for fruit and nut tree matrices for indaziflam and FDAT) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for indaziflam.

C. Response to Comments

EPA received a comment to the notice of filing which said that pesticide residues should not be increased. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

V. Conclusion

Therefore, tolerances are established for residues of indaziflam, N-[(1R, 2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl-1,3,5-triazine-2,4-diamine]-6-(1-fluoroethyl) and its fluoroethyl-indaziflam metabolite, each expressed as the parent compound, in or on coffee, green bean at 0.01 ppm, banana at 0.01 ppm, and palm oil at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 10, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.653, alphabetically add the following commodities, redesignate footnote 1 as footnote 2, and add a new footnote 1 to the table in paragraph (a) to read as follows:

§ 180.653 Indaziflam; tolerances for residues.

(a) *General.* * * *

Commodity	**Parts per million**
* * *	* *
Banana[1]	0.01
Coffee, green bean[1]	0.01
* * *	* *
Palm, oil[1]	0.03
* * *	* *

[1]No U.S. Registrations as of 12/02/2013.

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[FR Doc. 2014-01363 Filed 01/28/2014 at 8:45 am; Publication Date: 01/29/2014]